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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Arlene RAMSINGH *et al.*

Serial No.: 09/879,572

Filing Date: June 12, 2001

For: COXSACKIEVIRUS B4 EXPRESSION
VECTORS AND USES THEREOF

Examiner: Donna C. Wortman

Group Art Unit: 1648

Customer No.

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PATENT TRADEMARK OFFICE

DECLARATION OF ARLENE I. RAMSINGH
PURSUANT TO 37 C.F.R. § 1.132f
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, the undersigned, declare as follows:

1. I am a co-inventor, along with Sadia S. Halim, of the above-referenced patent application, and am familiar with its contents.
2. I have read the Office Action mailed 4 December 2002. I understand that the Examiner has cited two of our own publications as prior art:
- (a) Halim *et al.*, AIDS Res Hum Retroviruses 16:1551-8 (2000)¹
 - (b) Halim *et al.*, Vaccine 19:958-65 (2001)²

The authors of Paper (a) are Sadia S. Halim, Doris N. Collins and Arlene I. Ramsingh. The authors of Paper (b) are Sadia S. Halim, Stephanie E. Ostrowski, William T. Lee and Arlene I. Ramsingh.

3. The U.S. Patent and Trademark Office rejected all or most of the claims under 35 U.S.C. §102(a), as being anticipated by each of these publications. Apparently, the Office has taken the position

¹ Full cite: Halim SS, Collins DN and Ramsingh AI., "A therapeutic HIV vaccine using coxsackie-HIV recombinants: a possible new strategy." *AIDS Research and Human Retroviruses* 16(15):1551-1558 (2000 Oct. 10)

² Full cite: Halim SS, Ostrowski SE, Lee WT, Ramsingh AI., "Immunogenicity of a foreign peptide expressed within a capsid protein of an attenuated coxsackievirus," *Vaccine* 19(7-8):958-65 (2001 Nov 22)

that, because the papers list additional authors, any invention disclosed in these papers was made by an entity other than "Arlene I. Ramsingh and Sadia S. Halim" less than a year before the filing date of this application.

4. At the time the cited papers were prepared, I was director of the research program carrying out the research that was described in these two papers and in the present application. Sadia S. Halim, my co-inventor, was a graduate student working in my laboratory who played a role in the conception of the invention claimed in the above-identified patent application.

- (a) Doris N. Collins was a collaborator and working on this project under my supervision. As a pathologist, Dr. Collins' role in this project was to assist in review and interpretation of histological slides of animal tissues. I confirmed her findings. Collins did not contribute to the design and construction of the vaccine vectors or other claimed subject matter.
- (b) Stephanie E. Ostrowski was, at the time, a summer intern, employed by me and working under my supervision to test a different approach for making one particular vector - which was not successful - though her efforts were rewarded with co-authorship.
- (c) William T. Lee was a collaborator working on this project under my supervision. As a cellular immunologist, Dr. Lee helped with the technical conduct of some of the immunological assays. He did not contribute to the design and construction of the vaccine vectors or other claimed subject matter.

Collins, Ostrowski and Lee were named as co-authors of the above publications because it is the practice in our laboratory to give credit in the form of co-authorship to those members of the laboratory and collaborators who contribute to a project, even if their contribution falls short of conception of any new invention.

5. The disclosure in these two papers was a result of a project which only I and Sadia Halim had conceived and directed. Although all the co-authors discussed the work as it progressed, and Collins, Ostrowski and Lee exerted significant efforts in carrying out their relatively minor aspects of the overall project, their laboratory activities were completely under my supervision. I reviewed all their laboratory results, analyzed and interpreted them. I and Sadia Halim decided upon the next steps to be taken, informing Collins, Ostrowski and Lee of our wishes.

6. Based on the facts that I and Sadia Halim provided to our original patent attorney who was preparing this application, and his understanding of those facts, our attorney determined that I and Sadia Halim were the only co-inventors of the claimed subject matter and so the application was filed naming us as the inventive entity.

7. Collins, Ostrowski and Lee did not contribute in any way to the conception of the invention as presently claimed in this patent application. Despite their being listed as co-authors of both Halim *et al.* papers, all of the inventive subject matter set forth in these publications was the fruit of my Sadia Halim's inventive efforts.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

06/01/03

Date


Arlene I. Ramsingh